

REMARKS/ARGUMENTS

Claims 1-18 are pending and rejected as obvious under 35 U.S.C. §103(a) in view of *Hara* (EP 1 224 937 A1). Applicants respectfully traverse this rejection.

The claimed invention relates to a composition for repairing injured skin comprising: (a) 50 to 90% by weight of saccharide, (b) 0.5 to 10% by weight of povidone-iodine, (c) 0.1 to 20% by weight of water, and (d) 0.3 to 5% by weight of phospholipid (claim 1). *Hara* discloses a formulation for treating wounds comprising: (a) 50 to 90% sugar, (b) 0.5 to 10% iodophor, (c) 0 to 21% water, and (d) 0 to 40% hydrogenated lecithin (Abstract, [0008], [0009], [0021]-[0026]). As stated in the Office Action dated March 25, 2008, “it is the Examiner’s opinion that the determination of optimal or workable range of lecithin by routine experimentation is obvious absent a showing of criticality of the claimed range” and “the Examiner notes that Applicant has not provided any evidence of the criticality of the herein claimed range of phospholipid” (page 6, last paragraph).

In view of the Examiner’s position and as a showing of the criticality of the claimed phospholipid range, Applicants submitted supplemental data on October 27, 2008 (via Declaration), supporting Applicants’ assertion of non-obviousness. However, even though the supplemental data was entered and considered by the Examiner, the Advisory Action dated November 19, 2008, indicated that “the evidence presented to demonstrate the criticality of the claimed range of phospholipid demonstrates a difference in degree of the stirring aptitude and extensibility and not a difference in kind”.

Contrary to the Office’s position, the differences in the properties observed are more than mere differences in degree. Applicants submit herewith the Declaration of Dr. Takahito Kimura, the Director of Laboratory in the field of External Pharmaceutical at Teika Pharmaceutical Co. Ltd. for twelve years and a named inventor of the above-identified

application, as evidence of the meaningful differences obtained in ointment preparations that fall within the claimed parameters and those that do not.

As explained in the Declaration submitted herewith, “stirring aptitude and extensibility can be assigned four ranks: very easily stirred/extensible, easily stirred/extensible, difficult to stir/extend, and very difficult to stir/extend. These ranks indicate perceptible differences in their respective properties. By their very perception, these differences in stirring aptitude and extensibility are meaningful differences in ointment preparations.” As explained in M.P.E.P. 716.02: “unexpected results for a claimed range as compared with the range disclosed in the prior art had been shown by a demonstration of "a marked improvement, over the results achieved under other ratios, as to be classified as a difference in kind, rather than one of degree” (*In re Waymouth*, 499 F.2d 1273, 1276, 182 USPQ 290, 293 (CCPA 1974). Accordingly, the Office’s maintained conclusion of obviousness based on the assertion that the evidence presented was a difference in degree and not a difference in kind is flawed.

Furthermore, the assertion by the Office that the “the difference in degree between very easily stirred and easily stirred in comparing the products of the invention with Supplemental Product 1 is considered to be within experimental variations” does not take into account that such differences in stirring aptitude and extensibility are meaningful differences in the field of ointment preparations (see Declaration). Such meaningful differences are equivalent to “marked improvements” (see *In re Waymouth*), not “experimental variations”. Accordingly, Applicants’ claimed ointment compositions that exhibit these marked improvements over the art of record (i.e., *Hara*) are non-obvious in view of such art.

In addition, Applicants point out M.P.E.P. 2142 which states: “The ultimate determination of patentability is based on the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence.

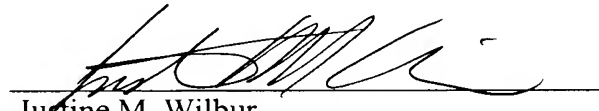
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Reply to Office Action of March 25, 2008

In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The legal standard of "a preponderance of evidence" requires the evidence to be more convincing than the evidence which is offered in opposition to it. With regard to rejections under 35 U.S.C. 103, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e., the reference teachings establish a *prima facie* case of obviousness) is more probable than not." As the Office has not provided evidence that the claimed ointment compositions do not provide marked improvements (as alleged by the Examiner), and Applicants' have offered evidence that the claimed compositions do provide marked improvements, Applicants' evidence in opposition to the Examiner's opinion meets "a preponderance of the evidence" to overcome the obviousness rejection.

Accordingly, Applicants request withdrawal of the obviousness rejections over *Hara*.

Respectfully submitted,

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